REMARKS

The above amendments and these remarks are responsive to the Office action dated September 5, 2008. Claims 1–25, 33, and 35–45 are pending in the application. Claims 1–25, 33, and 35–45 are rejected. By way of the present amendment, claim 45 has been amended. In view of the amendments above, and the remarks below, applicant respectfully requests reconsideration of the application under 37 C.F.R. § 1.111 and allowance of the pending claims.

Rejections under 35 USC § 103 : Claims 1–25, 33, and 35–44

Claims 1–15, 18–20, 24, 25, 33 and 37–43 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Tom (U.S. Patent No. 7,211,063) in view of Glines (US Patent No. 6,716,190). Claims 16, 17, 21–23, 35, 36 and 44 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Tom in view of Glines and further in view of Paskar (US Patent No. 6,623,449).

Applicant respectfully points out that the Examiner bears the burden of factually supporting any *prima facie* conclusion of obviousness. To reach a proper obviousness determination, the Examiner must consider the prior art from the point of view of a person of ordinary skill in the art at the time the invention was made; that is, at a time when the invention was unknown and just before it was made. The Examiner must then make a determination whether the claimed invention, as a whole, would have been obvious at that time to that person. When making this determination, knowledge of the disclosure in the applicant's own application must be put aside, in order to avoid the danger of impermissible hindsight, because the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention.

The *prima facie* case of obviousness must be reached on the basis of the facts

gleaned from the prior art. *Prima facie* obviousness cannot be established with mere conclusory statements. Rather, the Examiner must provide some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

Claim 1 and its Dependent Claims

Claim 1 recites a needle-free jet injection device for delivering a fluid into an internal organ. The needle-free jet injection device of claim 1 includes, amongst other structure, a rigid end effector that has

> a blunt distal end and a longitudinal axis configured into a shape and including a plurality of orifices, the end effector including a rigid interior wall that defines a rigid fluid channel, where the end effector is sufficiently rigid to maintain the shape of its longitudinal axis during use, where the fluid channel has a cross section through which a central axis of the end effector extends, and where the end effector is configured to enable fluid to flow from the fluid channel out through the plurality of orifices.

Claim 1 further recites that the rigid end effector "extends away from the ejection mechanism such that an operative end of the end effector is spaced from the ejection mechanism."

In the Office action, claim 1 was rejected based on a proposed combination of Tom with Glines. According to page 2 of the Office action, "Tom discloses the device substantially as claimed including a device that is capable of being used <u>for</u> needle-free jet injection for delivering a fluid into an internal organ ..." (emphasis added). On page 3 of the Office action, the Examiner asserts that Tom discloses a "<u>rigid end effector</u> having a blunt distal end and a longitudinal axis configured into a shape" (emphasis added), with the end effector "including a rigid interior wall," and "that the end effector is substantially rigid to maintain the shape of its longitudinal axis during use."

However, as will be more fully discussed below, Tom does not disclose a needle-

free jet injection device with a rigid end effector, as recited in claim 1. In recognition of the fact that "Tom does not specifically disclose physical elements pertaining to needle-less injection such as a fluid reservoir, lumen, plurality of orifices, etc." (page 3) the Office action proposed combining Tom with Glines. Even if Tom could properly be combined with Glines, as proposed in the Office action, the proposed combination still does not disclose a needle-free jet injection device with a rigid end effector, as recited in claim 1.

As an initial matter, Applicant respectfully points out that the device shown in Fig. 1 of Tom (reproduced below) is not a needle-free jet injection device. Rather, Tom discloses a pressure sensor for a therapeutic delivery device. As shown in Fig. 1 and generally described at column 2, line 65 to column 3, line 34, Tom discloses an apparatus 44 for accessing a patient's tissue or organ region 47. The apparatus 44 includes a rigid shaft 46, which may have a curved section, a sensor device 20, and a handle 48. As shown in Fig. 2, the force contact transducer or sensor device 20 includes a cap 30 and a bio-compatible coating or cover 40. The force contact transducer or sensor device 20 is desirably sealed to "prevent ingress of bodily or other fluids into the electrical regions of the apparatus" (column 4, lines 53–55). The cover 40 also "prevent[s] fluid ingress" (column 5, lines 13–16).

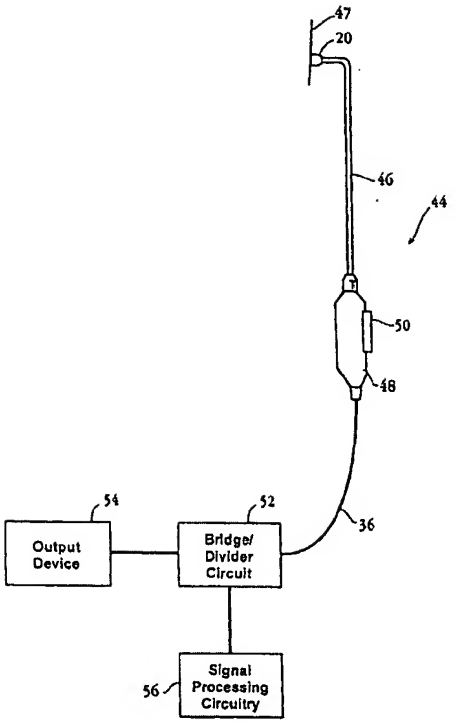


Fig. 1

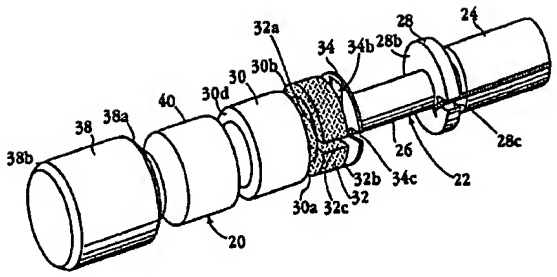


Fig. 2

As described at column 3, lines 35–48 of Tom, "handle 48 may be designed to produce a selected therapeutic effect on target tissue, when a desired pressure and/or pressure contact angle is sensed between the probe and target tissue." In particular and as cited by the Examiner in the Final Office action, the "therapeutic effect may be, for example, the injection, by a needle or needleless injection system" (column 3, lines 38–39). However, Tom does not disclose any structures or details of such a "needleless injection system." Rather, at column 3, lines 44–48, Tom merely makes a vague general reference that the "apparatus may therefore be equipped, according to well-known devices, to provide an extendable needle, a light fiber, an extendable mechanical-injury device, or the like to produce the desired therapeutic effect, in response to a signal applied by the user to handle 48." The mere naming of a

"needleless injection system" and a vague general reference to an apparatus "equipped, according to well-known devices" does not disclose, teach or suggest any structures or details regarding those devices.

Contrary to the statement on page 2 of the Office action that the device shown in Fig. 1 of Tom is capable of being used for needle-free jet injection, applicant respectfully points out that the device shown in Fig. 1 of Tom is merely a pressure sensor that may be used with a therapeutic delivery device (abstract, column 2, lines 30–35, column 3, lines 35–58), such as a needle-less injection system (column 3, lines 39–40). In particular, Tom merely discloses that an "effector may be operatively disposed on the probe for producing a given effect on the patient region when the effector is activated" (column 2, lines 31–33).

Tom clearly provides that the probe of the pressure sensing device shown in Fig. 1 is not itself an "effector." Rather, the probe of the pressure sensing device shown in Fig. 1 is merely used with an effector (such as a needle-less injection system) that is not shown in Fig. 1. Thus, Tom discloses that the effector, which is not shown in Fig. 1, produces a given effect on the patient. The probe of the pressure sensing device shown in Fig. 1 does not itself produce an effect on the patient. The fact that a pressure sensor (i.e., the device shown in Fig. 1 of Tom) may be used with a needle-less injection system does not transform the pressure sensor, itself, into a device for needle-less injection. Rather, a pressure sensor for use with a needle-less injection system, as suggested in Tom, merely assists an operator of the needle-less injection system.

Thus, Tom discloses no details of any needle-free jet injection device. Rather, Tom merely discloses the existence of needle-free jet injection devices (column 3, lines

39–40). Selectively attributing various details of the pressure sensing device shown in Fig. 1 of Tom to a needle-free jet injection device, with which the pressure sensing device may be used, impermissibly relies on the hindsight vision afforded by applicant's claimed invention. Accordingly, Tom does not disclose, teach or suggest a needle-free jet injection device with a rigid end effector, as recited in claim 1, because Tom does not disclose that a needle-free jet injection device includes any particular features, such as a rigid end effector.

Applicant respectfully disagrees with the assertion on page 4 of the Office action that "it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Tom by looking to Glines for the well known physical elements that make up a needle-less injector, such as the reservoir, orifices, fluid channel, etc." As noted above, Tom does not disclose, teach or suggest any particular structures for a needle-free jet injection device, such as the rigid end effector recited in claim 1, so there is no detailed structure in Tom that one of ordinary skill in the art at the time of the invention could have modified by looking to Glines. Accordingly, there was no rational reason for one of ordinary skill in the art at the time of the invention to have modified Tom by looking to Glines.

Furthermore, even if Tom could properly be combined with Glines, as proposed in the Office action, the proposed combination still does not disclose a needle-free jet injection device with a rigid end effector, as recited in claim 1, because Glines also does not disclose, teach or suggest a needle-free jet injection device with a rigid end effector, as recited in claim 1. Contrary to the statements on page 7 of the Office action, Figs. 8A–8C of Glines do not show an end effector (rigid or otherwise). Instead, Figs. 8A and

8C show an ampule (reference number 204 in Fig. 8A and reference number 221 in Fig. 8C), which houses, or is, the reservoir (reference number 223 in Fig. 8C). Accordingly, Figs. 8A–8C of Glines do not show an end effector that extends away from the ejection mechanism, as recited in claim 1.

For at least the reasons discussed above, the cited references, either alone or in combination, do not disclose, teach or suggest a device as claimed in claim 1. Claims 2–18, 33 and 35–43 depend from claim 1. Claims 2–18, 33 and 35–43, each of which contains further limitations that distinguish the cited references, are thus allowable for at least the reasons stated above with respect to claim 1. Accordingly, claim 1 and its dependent claims patentably distinguish the cited art, and Applicant respectfully requests that the rejections of claims 1–18, 33 and 35–43 under 35 U.S.C. § 103 be withdrawn.

Claims 14 and 15

Claims 14 and 15 recite that a distal section of the rigid end effector lies at an angle relative to the shaft of the end effector. Accordingly, claims 14 and 15 recite an end effector that (1) has a blunt distal end, (2) is rigid, (3) has a central axis of the end effector extending through a cross section of the fluid channel, and (4) has a distal section that is angled relative to the shaft. As noted above, Tom does not disclose any particular details of an effector. Furthermore, Glines does not disclose an end effector with a distal section that is angled relative to the shaft and that has a central axis that extends through a cross section of the fluid channel. In contrast, the injection system shown in Fig. 8D of Glines includes a flexible tubing 240 for transporting solution to the dispersion fixture 234. Furthermore, the central axis of the injection system does not

extend through a cross section of the flexible tubing 240 because the flexible tubing 240, is spaced away from the shaft 242 and the dispersion fixture 234 where it links these components.

For at least these additional reasons, the cited references, either alone or in combination, do not disclose, teach or suggest a device as claimed in claims 14 and 15. Accordingly, claims 14 and 15 patentably distinguish the cited art, and Applicant respectfully requests that the rejections of claims 14 and 15 under 35 U.S.C. § 103 be withdrawn.

Claims 41–43

Claim 41 recites that "at least a portion of a longitudinal axis of the distal section is not collinear with a longitudinal axis of the straight shaft section of the end effector." Accordingly, claim 41 recites an end effector that (1) has a blunt distal end, (2) is rigid, (3) has a central axis of the end effector extending through a cross section of the fluid channel, and (4) has at least a portion of a longitudinal axis of the distal section that is not collinear with a longitudinal axis of the straight shaft section of the end effector. As noted above, Tom and Glines, either alone or in combination, do not disclose such an end effector.

For at least these additional reasons, the cited references, either alone or in combination, do not disclose, teach or suggest a device as claimed in claim 41. Claims 42 and 43 depend from claim 41 and are thus allowable for at least the reasons stated above with respect to claim 41. Accordingly, claim 41 and the claims dependent therefrom patentably distinguish the cited art, and Applicant respectfully requests that the rejections of claims 41–43 under 35 U.S.C. § 103 be withdrawn.

Claim 19 and its Dependent Claims

Claim 19 recites an end effector for a needle-free injection device adapted to inject a fluid through an outer surface of an internal organ and into the internal organ, without penetration of the outer surface of the internal organ by the end effector and while maintaining functionality of the organ. The end effector of claim 19 comprises:

> a longitudinally rigid elongate shaft that extends away from the injection device to a blunt distal end and that includes a tubular fluid channel fluidly and directly coupled with a plurality of orifices through which the fluid may be ejected, wherein the elongate shaft is sufficiently rigid to maintain a longitudinal shape during use, where the tubular fluid channel has a cross section through which a central axis of the end effector extends, and where the tubular fluid channel includes a rigid portion extending substantially all the way between the injection device and the plurality of orifices.

For at least the reasons discussed above, Tom and Glines, either alone or in combination, do not disclose, teach or suggest an end effector as claimed in amended claim 19. Claims 20–25 and 44 depend from claim 19. Claims 20–25 and 44, each of which contains further limitations that distinguish the cited references, are thus allowable for at least the reasons stated above with respect to claim 19. Accordingly, amended claim 19 and its dependent claims patentably distinguish the cited art, and Applicant respectfully requests that the rejections of claims 19–25 and 44 under 35 U.S.C. § 103 be withdrawn.

Claims 24 and 25

Claim 24 recites that the distal section of the rigid end effector is angled relative to the straight section of the rigid end effector. Claim 25 recites that the distal section of the rigid end effector is curved. As noted above, Tom and Glines, either alone or in combination, do not disclose, teach or suggest a rigid end effector with a distal section that is curved or is angled relative to the straight section of the rigid end effector.

Accordingly, claims 24 and 25 patentably distinguish the cited art, and applicant respectfully requests that the rejections of claims 24 and 25 under 35 U.S.C. § 103 be withdrawn.

Rejection under 35 U.S.C. § 103 : Claim 45

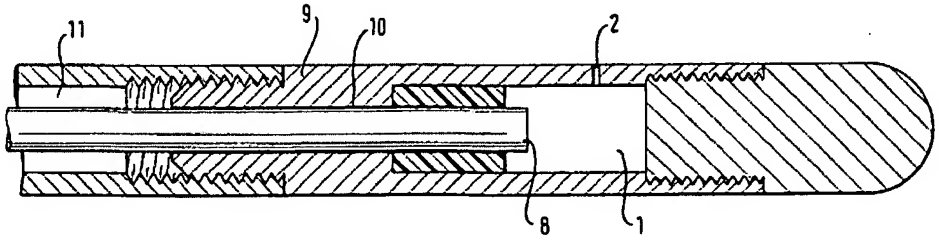
Claim 45 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Menne et al. (U.S. Patent No. 5,840,061) in view of Tom. Applicant disagrees with the rejection. However, Applicant has nonetheless made certain claim amendments to clarify what Applicant regards as his invention. In particular, applicant has amended claim 45 to recite that the longitudinally rigid elongate member of the needle-free jet injection device includes, amongst other structure, a central longitudinal axis and "a fluid channel extending substantially all the way from the body to the at least one injection orifice, wherein the central longitudinal axis is within the fluid in the fluid channel substantially all the way from the body to the at least one injection orifice." Although applicant believes that the original language of claim 45 (i.e., that the fluid channel has a cross section through which the central longitudinal axis extends) carried such meaning, applicant has amended the claims in the hope of advancing prosecution.

Menne et al. does not disclose a needle-free jet injection device that includes a longitudinally rigid elongate member with a fluid channel extending substantially all the way from the body to the at least one injection orifice, wherein the central longitudinal axis is within the fluid in the fluid channel substantially all the way from the body, within which an ejection mechanism is disposed, to the at least one injection orifice. Rather, Applicant respectfully points out that Menne et al. discloses a fluid channel that has an annular cross section such that the longitudinal axis is not within the fluid in the fluid

channel substantially all the way from the body, within which an ejection mechanism is disposed, to the at least one injection orifice.

As shown in Figs. 2 and 3 of Menne et al. (reproduced below), the distal end of a working piston or probe 8 delimits a pressure chamber 1 that contains liquid flowing into an ejection opening 2 (column 4, lines 56–62). A "narrow liquid flow-through slit 10" remains between the probe 8 and the guiding member 9 where the probe 8 passes through the guiding member 9, with the liquid flow-through slit 10 running "into a liquid supply channel 11 surrounding the probe 8" (column 5, lines 3–8). Furthermore, the probe 8 is solid, such that the liquid flow-through slit 10 and liquid supply channel 11 are fluid channels with annular cross sections. As shown in Figs. 2 and 3 of Menne et al., the annular liquid flow-through slit 10 and liquid supply channel 11 are both approximately centered relative to the guiding member 9 such that a central longitudinal axis of the guiding member 9 would <u>not</u> be within the fluid in the fluid channel (i.e., the liquid in the liquid flow-through slit 10 and the liquid supply channel 11) substantially all the way from the body, within which the ejection mechanism is disposed, to the at least one injection orifice, as recited in claim 45. Rather, the central longitudinal axis of the guiding member 9 would be within the probe 8.

Fig. 2



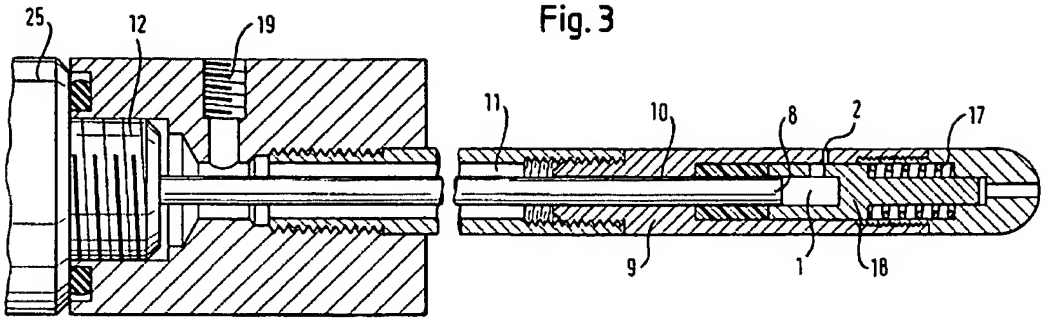
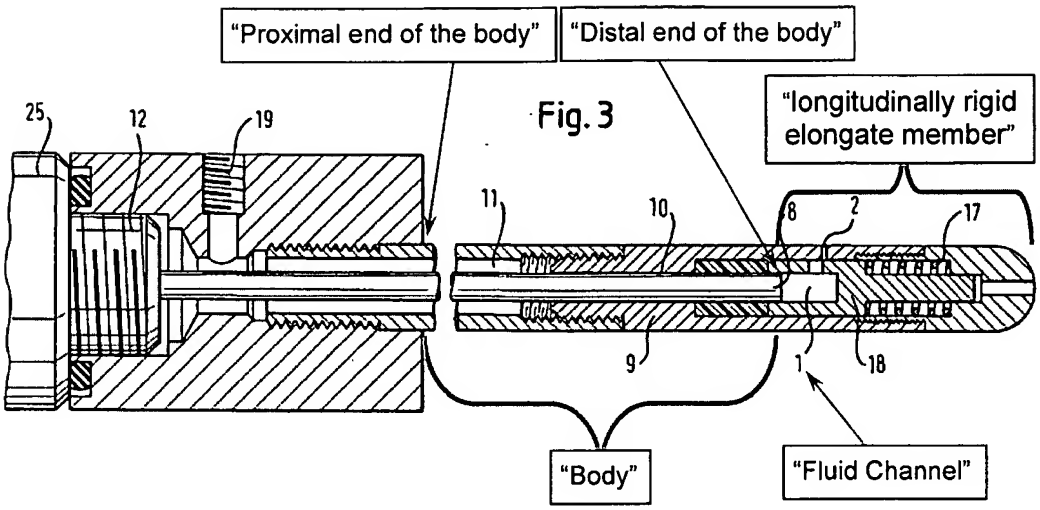


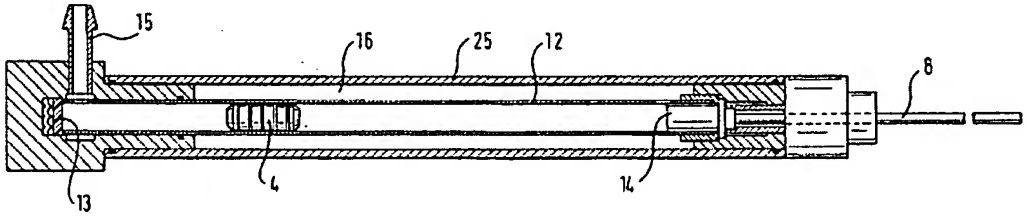
Fig. 3

In recognition of the annular cross section of the fluid channel in Menne et al. (i.e., the liquid flow-through slit 10 and the liquid supply channel 11), the Office action at page 11 has construed the pressure chamber 1 of Menne et al. to be a "fluid channel extending substantially all the way from the body to the at least one injection orifice." In particular, the Office action, at page 10, has defined the body to be "the proximal end portion of 9" with the "proximal end of the body starting where it screws into the block portion where 19 is located" and the distal end of the body has been defined to be "the portion where rod 8 ends and the unobstructed portion of cavity 1 begins." The Office action, at pages 10–11, defines the longitudinally rigid elongate member to be "the portion of 9 where rod 8 ends and cavity portion 1 begins and extends all the way to the distal tip of 9." Applicant provides below an annotated version of Fig. 3 from Menne et al. to show the "body" and "longitudinally rigid elongate member" as interpreted on pages 10–11 of the Office action.



Applicant respectfully disagrees with these interpretations of "body" and "longitudinally rigid elongate member." In particular, claim 45 also recites that an ejection mechanism is disposed within the body. Applicant respectfully submits that, even if the indicated portion of the device shown in Fig. 3 of Menne et al. could properly be interpreted as a "body," there is no "ejection mechanism" disposed within such a "body". On page 11 of the Office action, the driving piston 4 (shown in Fig. 1 of Menne et al., which is reproduced below) is interpreted to be the "ejection mechanism."

Fig. 1



However, the driving piston 4, which impacts the proximal end of the probe 8 (the left end of the probe 8 in Fig. 1), as described at column 5, lines 33–43, is not in the "body" as interpreted on pages 10–11 of the Office action and shown in the annotated version

of Fig. 3 reproduced above. Accordingly, Menne et al. does not disclose a longitudinally rigid elongate member with a fluid channel extending substantially all the way from a body to at least one injection orifice, wherein the central longitudinal axis of the longitudinally rigid elongate member is within the fluid in the fluid channel substantially all the way from the body, within which an ejection mechanism is disposed, to the at least one injection orifice, as recited in claim 45.

Furthermore, as recognized in the Office action, Menne et al. does not disclose that at least a portion of a longitudinal axis of the distal section of the longitudinally rigid elongate member is not collinear with a longitudinal axis of the straight shaft section of the longitudinally rigid elongate member. As discussed above, Tom does not disclose any particular details of an effector, such as a needle-free jet injection device. Rather, Tom merely discloses the existence of needle-free jet injection devices. Furthermore, Fig. 1 of Tom does not show a therapeutic delivery device. Rather, Fig. 1 of Tom merely shows a pressure sensor that may be used with a therapeutic delivery device. Thus, there was no rational reason for one of ordinary skill in the art at the time of the invention to have looked to Tom for suggestions to modify the device of Menne et al. Accordingly, Menne et al. and Tom, either alone or in combination, do not disclose a needle-free jet injection device as recited in claim 45.

Thus, for at least the reasons discussed above, the cited references, either alone or in combination, do not disclose, teach or suggest a needle-free jet injection device as claimed in claim 45. Accordingly, claim 45 patentably distinguishes the cited art, and Applicant respectfully requests that the rejection of claim 45 under 35 U.S.C. § 103 be withdrawn.

Conclusion

Applicant believes that this application is now in condition for allowance, in view of the above amendments and remarks. Accordingly, applicant respectfully requests that the Examiner issue a Notice of Allowability covering the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.

Respectfully submitted,

KOLISCH HARTWELL, P.C.

/Steven W. Hudnut/

Steven W. Hudnut
Registration No. 57,786
Customer No. 23581
520 S.W. Yamhill Street, Suite 200
Portland, Oregon 97204
Telephone: (503) 224-6655
Facsimile: (503) 295-6679
Attorney/Agent for Applicant/Assignee

CERTIFICATE OF ELECTRONIC TRANSMISSION

I hereby certify that this correspondence is being filed electronically via the EFS-Web system at www.uspto.gov on March 5, 2009.

/Merissa R. Anderson/
Merissa R. Anderson